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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,078	03/24/2004	Mark Tsonton	END-5293	7086

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EXAMINER	
SMITH, FANGEMONIQUE A	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,078	TSONTON ET AL.	
	Examiner	Art Unit	
	FANGEMONIQUE SMITH	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4, 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on June 30, 2006. The Examiner acknowledges the cancellation of claims 2, 3 and 5-7; and amendment of claim 1. Claims 1, 4 and 8-20 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 8, 9, 12-14 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (U.S. Patent Number 6,758,824).

In regard to claims 1, 8, 9 and 12-14, Miller et al. disclose a tissue cutting device having a distal segment and a proximal needle segment. Miller et al. suggest the proximal needle segment is formed of a metallic MRI compatible material such as titanium (col. 6, lines 50-67; col. 7, lines 1-2). The distal needle segment of the Miller et al. device includes a tissue receiving port (43) and is made of non-metallic material (col. 8, lines 22-60). Miller et al. further disclose the proximal needle segment joined with the distal needle segment along a common longitudinal axis, forming a continuous cutter lumen.

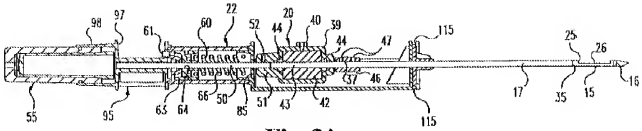

Fig. 3A

Miller et al. disclose the continuous lumen formed by the distal needle portion and the proximal needle portion creates a vacuum lumen and allows vacuum pressure to be maintained during use (col. 7; col. 8, lines 1-21). The lumen comprises at least one passage extending to an outer surface of the needle. The device disclosed by Miller et al. includes a distal piercing tip (16) located distally from the tissue receiving port.

In regard to claims 16-19, Miller et al. disclose a biopsy device for use with a magnetic resonance imaging machine. The device comprises a distal needle segment (50) as shown in Figure 3A. This distal needle segment has a lateral tissue receiving port (55) and is distal from the target site when the device is in operation. Miller et al. suggest the distal needle segment may be formed of a non-metallic material (col. 6, lines 50-67; col. 7, lines 1-2). The device disclosed by Miller et al. further includes a proximal needle segment (15), which is formed at least in part of a metal. Miller et al. disclose the distal needle segment being coupled to the proximal needle segment. Furthermore, the two coupled segments create a continuous lumen between the distal and proximal cutter portions of the device (col. 7; col. 8, lines 1-21).

The tissue receiving port has a proximal edge located where the port connects to the aspiration tube. The proximal edge of the tissue receiving port is at least 0.5" spaced apart from the proximal needle segment (col. 19, lines 15-26).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Humphrey (U.S. Patent Number 5,607,401). In regard to claims 4 and 20, Miller et al. disclose the features of the Applicant's invention as described above. Although Miller et al. disclose joining the distal needle segment with the proximal needle segment, Miller et al. do not disclose having the distal needle segment molded over a portion of the proximal needle segment. Humphrey discloses a piercing device for penetrating into a body cavity of a patient. Humphrey further discloses attaching two segments of the needle together through a molding process. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by Miller et al., to include a needle made of two segments joined through a molding process, similar to that

disclosed by Humphrey, to construct a continuous device while providing a secure and sealed joint between the two members.

6. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Frederick et al. (U.S. Patent Number 6,017,356).

In regard to claims 10 and 11, Miller et al. disclose the features of the Applicant's invention as described above. Although Miller et al. suggest portions of the device be made of alternative materials, such as plastics or other non-metallic substances, to be compatible with magnetic resonance imaging systems, Miller et al. do not disclose having a piercing tip made of ceramics or glass material. Frederick et al. disclose a cutting device for penetrating into a body cavity of a patient. Frederick et al. further discloses the penetrating device being made of a ceramic material (col. 13, lines 28-57). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by Miller et al., to include a penetrating tip portion made of ceramic material, similar to that disclosed by Frederick et al., to construct the device of a biocompatible material, while maintaining the functionality of the device.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Gregoire et al. (U.S. Patent Number 5,944,673).

In regard to claim 15, Miller et al. disclose the features of the Applicant's invention as described above. Miller et al. do not disclose having multiple passages extending from the vacuum to an outer surface of the needle. Gregoire et al. disclose a biopsy instrument with a vacuum source

and an outer elongated hollow piercing needle. The needle of the Gregoire et al. device further includes a plurality of tissue receiving ports. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by Miller et al., to include a multi-port needle, similar to that disclosed by Gregoire et al., to allow sampling of multiple tissue samples from a tissue site (Gregoire - col. 6, lines 17-39).

Response to Arguments

8. Applicant argues the Miller et al. reference does not disclose a distal needle segment formed of a non-metallic first material and a proximal needle segment made in part of a metallic second material. Examiner respectfully disagrees. As shown in Figure 3A, the distal needle segment is shown on the left, with the tissue receiving port (43) within the housing (39). Miller et al. suggests this part of the apparatus being formed of a non-metallic material (col. 8, lines 22-45). Miller et al. also disclose a proximal needle segment shown to the right of the housing (39) comprising cannula 15 and the trocar tip (16). The proximal needle segment is made of a metallic material and is joined to the distal needle segment. The joint at a proximal end of the inner cannula (17) and a distal end of the tissue receiving port (43) is secured by a coupler (46) made of a plastic material forming an airtight seal between the two needle segments (col. 7, lines 3-67; col. 8, lines 1-45). A continuous lumen is formed upon the two segments being joined along a common longitudinal axis. Applicant's arguments filed September 21, 2007 have been fully considered but they are not persuasive. The rejection stands.

9. Applicant argues the Miller et al. reference does not disclose the metal of the device being positioned about 0.5" from a proximal edge of the tissue receiving port. Examiner respectfully disagrees. Miller et al. disclose a proximal needle segment (15), which is formed at least in part of a metal coupled to a distal needle segment. Upon coupling the two segments, a continuous lumen between the distal and proximal cutter portions of the device is created (col. 7; col. 8, lines 1-21). A tissue receiving port of the distal needle segment has a proximal edge located where the port connects to the aspiration tube (col. 8, lines 4-45). The proximal edge of the tissue receiving port is at least 0.5" spaced apart from the proximal needle segment (col. 19, lines 15-26). Applicant's arguments filed September 21, 2007 have been fully considered but they are not persuasive. The rejection stands.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FANGEMONIQUE SMITH whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736